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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE HONORABLE BOARD OF PATENT APPEALS AND INTERFERENCES

In re the Application of Joesph Robrerts et al.
Application No.: 09/972,245
Filed: October 9, 2001
Docket No.: 078728-0104

For: **PROTECTING THERAPEUTIC COMPOSITIONS FROM HOST-MEDIATED INACTIVATION**

REPLY TO EXAMINER'S ANSWER

Appeal from Group 1635

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SUMMARY OF THE ARGUMENT

The measuring of "antigenicity" and "immunogenicity," which the examiner alleges is taught by the cited prior art, does not constitute "assaying a biological activity," as recited in the appealed claims.

II. ARGUMENT

All of the pending rejections hinge upon the examiner's assertion that the cited prior art's measurement of "antigenicity" or "immunogenicity" of a therapeutic agent constitutes "assaying a biological activity" of the therapeutic agent. *See, e.g.* Examiner's Answer, pg. 12, ¶¶ 1-2; pg. 14, ¶¶ 1-2; pg. 15, ¶ 2. The examiner's assertion is factually and legally erroneous, however.

As a matter of fact, the cited art's measurements of antigenicity and immunogenicity of a therapeutic agent do not constitute assaying a biological activity of the therapeutic agent. Rather, the cited art employed assays measuring antigenicity or immunogenicity of a therapeutic agent to gauge features unrelated to the cellular or physiological responses intended by administration of the therapeutic agent to alleviate, reduce or remove symptoms of the targeted disease or condition. The evaluated features not only were unrelated to the intended functionalities but also were concerned with undesired consequences of administering foreign agents into a host.

For example, Deckert considered modifications to a humanized A33 antibody (huA33) designed to treat colon cancer. According to the examiner, Deckert's attempts to measure antigenicity equate to assaying for a biological activity of huA33 as presently claimed. Yet, the antigenicity of huA33 reflects nothing of its functionality, *i.e.*, to bind a cell-surface differentiation antigen of approximately 43 kDa expressed on most colon cancers. Indeed, it is the antigenicity and immunogenicity of the compound that Deckert hoped to reduce. *See, e.g.* pg. 382, col. 1, ¶¶ 1-2.

Chinol considered modifications to avidin. According to the examiner, Chinol's measurements of avidin's antigenicity equate to assaying for a biological activity of the therapeutic agent. As an initial matter, appellants note that Chinol does not even hint that avidin is a therapeutic agent. Instead, Chinol acknowledges that avidin is merely used in conjunction with therapeutic agents in immunotargeting and pretargeting protocols. *See, e.g.* pg. 189, col. 1-2; Abstract. As nothing in the record contradicts this point, Chinol does not

contain each of the claimed elements. Furthermore, besides the fact that avidin is not a therapeutic agent, avidin's antigenicity tells nothing about the compound's biological activity, namely, binding biotin.

The examiner's erroneous reading of the prior art extends as well to the combinations of Alvarez, Graham, Francis, Pederson, Roberts and Bollin, alleged to render the claimed invention obvious. Without citing any particular passage, the examiner contends that immunogenicity measurements for asparaginase supply the presently recited claim element of comparing the biological activities of first and second modified therapeutic agents. Examiner's Answer, pg. 15, ¶ 2; pg. 17, ¶ 2. In the proposed combinations, however, appellants can find no comparisons of immunogenicity measurements for first and second modified therapeutic agents. Even accepting the examiner's contention *arguendo*, moreover, does not change the fact that the immunogenicity of asparaginase foretells nothing of the compound's ability to hydrolyze L-asparagine into L-aspartic acid and ammonia. *Alvarez*, pg. 200, col. 1, ¶ 1.

Accordingly, the examiner's assertion that the cited art's measurement of "antigenicity" or "immunogenicity" of a therapeutic agent constitutes "assaying a biological activity" is factually erroneous.

In addition, the examiner's assertion is legally flawed. The Federal Circuit recently summarized the precepts of construing claim terms. *See Phillips v. AWH Corporation*, 415 F.3d 1303 (Fed. Cir. 2005) (*en banc*). In *Phillips*, the Court held that the specification "is the single best guide to the meaning of a disputed term", and usually is dispositive. *Phillips v. AWH Corporation*, 415 F.3d 1303, 1315 (Fed. Cir. 2005) (*en banc*), *quoting Vitronics Corp. v. Conceptronic, Inc.* 90 F.3d 1576, 1582 (Fed. Cir. 1996).

In the instant case, the specification expressly distinguishes measuring antigenicity and immunogenicity from the claimed invention. *See, e.g.* Application, pg. 2, ln. 16 to pg. 3, ln. 8. Nevertheless, the examiner attempts to construe "assaying a biological activity" so as to encompass the excluded measurements. Thus, the examiner's construction directly conflicts with the clear teachings of the specification and, hence, is legally flawed under *Phillips*. *Id.* at 1315 & 1316.

In summary, the examiner has committed both legal and factual errors in rejecting the pending claims. Accordingly, appellants renew their request that the Board overrule the subject rejections.

Respectfully submitted,

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